

Seeking consent for organ donation: Process evaluation of implementing a new Specialist Requester nursing role

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Title

Seeking consent for organ donation: Process evaluation of implementing a new Specialist Requester nursing role.

Abstract

Aim: To explain the differences in organ donation consent outcomes of a new nursing role (Specialist Requesters) derived from the United States compared with the existing nursing role (Specialist Nurses in Organ Donation).

Design: 30 month observational qualitative process evaluation: Implementation theory-informed analysis.

Methods: Qualitative content analysis of free text describing challenges, processes and practice from 996 bespoke routinely collected potential organ donor 'approach forms' from two regions: one where there was no difference, and one with an observed difference in consent outcomes.

Results: Region A consent rate: Specialist Requester 75.8%, Specialist Nurse in Organ Donation 71.8%. Region B consent rate: Specialist Requester 71.4%, Specialist Nurse in Organ Donation 82%. Region A Specialist Requesters turned the family position from no or uncertain to support organ donation in 73% of cases, compared with 27.4% in Region B. Two Specialist Requesters in region A were highly effective. Region B experienced problems with intervention fidelity and implementation.

Conclusions: The benefits of the Specialist Requester role remain unclear. Positive differences in consent rates achieved by Specialist Requesters in the originator region reduced over time and have yet to be successfully replicated in other regions.

Impact: The impact of Specialist Requesters on consent outcomes varied across regions and it was not known why. Specialist Requesters in region A were better at getting family member(s) to support organ donation. In region B, Specialist Nurse in Organ Donation consent rates were higher and problems with intervention fidelity were identified (recruitment, staffing, less experience). Policy makers need to understand it is not just a matter of waiting for the Specialist Requester intervention to work. Ongoing training and recruiting the right people with the right skills need to be addressed and consistently reviewed.

Keywords

Specialist Nurse in Organ Donation, Specialist Requesters, Designated Requesters, organ donation, consent, complex interventions, Implementation, process evaluation

INTRODUCTION

Nurses are at the forefront of seeking consent for organ donation in many global health settings. Specialist nurse positions in organ donation can be found in Spain (Miranda, Vilardell, & Grinyó, 2003) the Netherlands (Jansen et al., 2011) and Australia (Lewis, White, Bell, & Mehakovic, 2015) and the UK. They are expected to have a diverse set of skills including; clinical, primary care, bereavement support, administrative, organisational and logistical experience (Noyes et al., 2019). The U.S. has a hybrid model whereby any authorised person (including nurses) who has completed specialist training can legally approach a family whose relative has died about organ donation.

Consent rates for organ donation can and do still vary hugely within and between countries and on the whole, in spite of substantial investment to implement and accommodate these specialist roles, we know little about what is working, for whom and in what context. Learning more will help optimise opportunities to address the global health priority of increasing consent rates for deceased organ donation (“WHO | Donation and transplantation,” 2013).

In 2015 the UK implemented a new nursing role, the ‘Specialist Requester’ (the intervention) adapted from the U.S model but designed to fit around the UK organ donation system. The purpose of this paper is to report on the initial implementation of this role across two NHS Blood and Transplant (NHSBT) regions, and its effectiveness in increasing consent rates to organ donation (compared with the previous role) in the UK. More specifically, a process evaluation was required to better understand why the Specialist Requester intervention had thus far only increased consent rates in one UK region: it only made an observed difference in the original UK region that developed, championed, promoted and implemented it in the UK. More detailed analysis of their routinely collected data was needed through the lens of implementation theory in order to better understand what happened, what worked and why.

BACKGROUND

The United States context and the Designated Requester role

The role of the Designated Requester was implemented in 1999 and was designed to increase deceased organ donation consent rates (Department of Health and Human Services, 2000). We have added additional contextual details which explain the US organ donation system in supplemental file 1. Evidence of the effectiveness of a Designated Requester compared with usual practice is however weak. Immediately after implementation Bires’ 1999 small comparison study of two hospitals in Pennsylvania, one with a Designated Requester and one using the Organ Procurement Organisation services (OPOs), saw an overall decrease in consent in both hospitals with Designated Requesters consent rates 2% lower than the OPOs (Bires, 1999). The literature published since has emphasised the benefits of the skill and experience of the person speaking to families about organ donation after their relative died. Shafer et al. 2003 have shown that having Designated Requesters improves the conversion of potential donors to actual donors in a study examining nine level one trauma centres and again later in an update review (Shafer, 2009). However, reports still show widely varying consent rates across OPOs from 59% to 76% in some regions (Goldberg, Halpern, & Reese, 2013). Nonetheless there is a growing body of literature (Chandler, Connors, Holland, & Shemie, 2017; Childress & Liverman, 2006; Ebadat et al., 2014; Nathan et al., 2003; Siminoff, Traino, & Genderson, 2015; Smith, 2003; Traino, Molisani, & Siminoff, 2017; Vincent & Logan, 2012; Wojda et al., 2017) concerning the influence of the person who requests organ donation, which highlights several characteristics of the Designated Requester thought to positively influence the consent rate;

- the experience of the person making the request,
- decoupling – notification of death as separate from request for donation – in addition to raising the issue of donation earlier,
- time spent with the family,
- discussing the benefits of donation,
- unapologetic language,

- confidence of the person making the request,
- sensitivity and compassion to the bereaved family members,
- ongoing effective communication training for novice and experienced requesters.

The most recent studies have however observed variation in communication skills of Designated Requesters in different US regions and that further research is needed to ensure standards of training and practices across all OPOs are delivered and upheld. (Traino et al., 2017).

In summary, overall we found a lack of rigorous evidence to show that Designated Requesters are more effective than other types of health service personnel in gaining consent for organ donation. A recent systematic review reiterated the lack of good evidence describing interventions for healthcare professionals that lead to higher numbers of organ donors (Witjes et al., 2019). Nonetheless, Designated Requesters continue to be actively promoted as a positive intervention to achieve desired consent rates at transplant conferences. It was at one such conference in the US that NHSBT Managers in the UK first learned about the Designated Requester role and wanted to explore implementing the role in a UK context to further improve consent rates (personal communication).

The United Kingdom context for organ donation

While there has been an increase in the United Kingdom rates of organ donation in recent years (NHSBT, 2017) the demand continues to outweigh the number of available organs for transplant. SNODs are specially trained to approach family members when their relative who died is eligible for organ donation. The role was implemented alongside the UKs 'Organ Donation Taskforce' in 2008 to address various critical issues with organ donation (Donation Taskforce, 2008). We have added additional contextual details in supplemental file 2.

Since 2008 the SNOD role has become associated with higher consent rates and a more positive experience for family members at especially traumatic times (Jansen et al., 2011). Nonetheless the UK still has high family refusal rates compared to other nations (Hulme et al., 2016; NHS Blood and transplant review board, 2017; Vincent & Logan, 2012) and there has been documented concerns within NHSBT about the SNOD role (Box.1).

Box.1 NHSBTs concerns about the SNOD role

- Higher rates of attrition than other specialist nursing roles,
- Long shift patterns and an increase in on call rotas,
- Emotional stress caused by long term engagement with the acutely bereaved,
- Increasingly widening and varied responsibility within NHSBT core services,
- Regional variations means that some SNODs have struggled to gain real expertise across the entire organ donation pathway,
- Regional variations means that some SNODS make significantly less 'approaches' to families when their deceased relative is a potential organ donor (Duncalf S & Ryan M, 2017).

Table 1 describes some of the differences and similarities of SNODs and Specialist Requesters under the UK model and Designated Requesters in the US model of organ donation.

Implementing the United States Designated Requester role in the United Kingdom

In April 2015 an adapted version of the US model of the Designated Requester was implemented in the UK as a way of addressing concerns with the SNOD role and increasing consent rates. Specialist Requesters (the title used in the UK) were implemented in an originator region, 'region A' from 13.04.15 to 31.12.15. A second region, 'region B' joined in December 2015. Four Specialist Requesters started in region A with a fifth joining 5 months after implementation. Four Specialist Requesters started in region B. Below (Table 2) we briefly summarise the intention of the Specialist Requester intervention in the UK (including any differences in training) using the TiDieR check list and guide (Hoffmann et al., 2014)

Initial NHS Blood and Transplant consent outcomes following the introduction of Specialist Requesters

The consent outcomes of initial implementation in 2 regions over 10 months from (13.04.15-09.03.16) (Poppitt et al., 2016) showed no statistical difference in consent rates of SNODs and Specialist Requesters. The role was subsequently rolled out into a further two regions. A direct comparison of consent rates within these 4 regions over a 12month timeframe (Oct16-Sep17) showed mixed results (Madden, 2017). There was no overall statistically significant improvement in consent rates across the four regions and overall the Specialist Requesters were no more effective at gaining consent than SNODs. Although the NHSBT analysis was not powered to show a statistically significant difference at regional level, results did however show a clear 19.5% difference in the consent rate favouring Specialist Requesters compared to SNODs in region A (figure.1).

Analysis of the initial implementation of Specialist Requesters compared with SNODs focussed on determining the overall effect on organ donor consent outcomes. In this paper we turn to analysing bespoke qualitative data collected by Specialist Requesters and SNODs alongside consent outcomes for a longer period of time (30 months 14.04.15 to 31.10.17) to try and explain what happened during initial implementation within and across regions A and B only to help explain why the intervention appeared to work to increase consent rates in region A but not elsewhere. We frame the analysis within implementation science theory in particular Diffusion of Innovation (Everett, 2003): how an innovation tends to spread through any given population and Normalisation Process Theory(May et al., 2015); how people respond, act or change to any given innovation.

THE STUDY

Aim

To analyse routinely collected bespoke qualitative NHSBT data in order to establish any similarities and differences in practice to help explain the regional variation in consent rates between Specialist Requesters compared with SNODs in region A compared with region B.

Design

The academic members of the joint research team were not involved in the adaptation, development or implementation of the Specialist Requester role in the UK, or in designing the initial implementation study or the routine collection of process data. Our academic involvement commenced when we were asked to analyse a large volume of qualitative routinely collected process evaluation data and consent outcomes to try and understand the differences in outcomes between two regions. We undertook a qualitative process evaluation involving analysis of text from bespoke routinely collected 'approach forms' at the time of contact or soon after with family members of all potential organ donor cases by Specialist Requesters and SNODs from 14.04.15 to 31.10.17 (30 months). When Specialist Requesters led the process in their intended new role, SNODs modified their role to fit with the lead role of the Specialist Requester in approaching the family and taking consent as described in Tables 1 and 2. When no Specialist Requester was available, the SNOD reverted to their old role and led the approach and consent process with families.

Theoretical perspective

We selected two theories through which to frame our thinking and the analysis. Diffusion of Innovation Theory (DoIT) (Everett, 2003), which seeks to explain how innovations are taken up in a population, and in particular to unpack the active mechanisms (that lead to social change) that could be observed within the data. We also used Normalisation Process Theory (NPT) (May et al., 2015), which is an Action Theory which seeks to understand what people do rather than their attitude or beliefs to provide greater understanding of the activities in NHSBT (primarily region A) during the 30 month implementation period (see Table 4).

Sample/participants

A rotating workforce of approximately 12 Specialist Requesters and 40 SNODs who approached family members of 996 potential organ donor cases, representing all cases over 30 months (14.04.15 to 31.10.17).

Data collection

The approach form

NHSBT originator region A developed a bespoke data collection tool for the pilot implementation. SNODs and Specialist Requesters from region A and B populated the 'approach form' for every family approached about organ donation. Information included on the forms related to processes involved before, during, and the outcome of the 'approach conversation' with family member(s) whose relative was eligible for organ donation. These 'approach forms' included headings to capture; referral details, mobilisation and attendance, assessment, family details, the approach, consent process, outcome and additional comments in a free text box. (appendix 1)

996 approach forms were routinely completed by Specialist Requesters and SNODs (in hard copy and in digital format on their iPads) from 14.04.15 to 31.10.17 (30 months) from region A and B teams, making 996 cases in total.

Ethical considerations

The study was conceived as an internal NHS health improvement service evaluation for which NHS ethics approval was not required. For the academic team to undertake an analysis of the bespoke routinely collected qualitative process evaluation data, a protocol and data sharing agreement were developed and jointly agreed by both parties (Bangor University and NHSBT). Ethics approval was granted from Bangor University (10.11.17) and from NHSBT CARE committee (17.10.17) and NHSBT Research, Innovation, Technology and Advisory (RINTAG) board (11.12.17). Only anonymised data were shared and the data sharing agreement outlined a set of principles for its custody, use and return to NHSBT.

Data analysis

Textual data from 996 approach forms were analysed. Approaches undertaken by a SNOD and Specialist Requester were anonymised and given a unique code to differentiate the role and the region. The following analysis plan was followed:

1. The approach form free text data in all the 996 approach forms were read by two researchers. We could not see any emerging ideas or explanations that would account for differences in practice or consent outcomes. We therefore decided to stratify and group approach forms for more in depth qualitative content analysis (Hsieh & Shannon, 2005) on data which documented a change in the family's initial feelings about organ donation and the eventual organ donation outcome. We undertook this stratification of approach forms as getting families to move to a position of supporting organ donation is key to a positive consent outcome, and the SNOD or Specialist requester's ability to change the family member's position on consent could help explain the difference in outcomes between regions A and B. Approach forms were stratified and coded as follows:

Families initial feelings about organ donation	Eventual organ donation consent outcome
1. Positive	1. Supported organ donation
2. Positive donation	2. Did not support the organ
3. Uncertain	3. Supported the organ donation
3. Uncertain donation	3. Did not support the organ
4. Negative	4. Supported the organ donation
5. Negative donation	5. Did not support the organ

We then specifically focussed on approach forms in cases where the family member(s) initial views changed to either supporting or not supporting the organ donation, and in cases where the family member(s) views remained negative. We further organised these specific approach forms by role (SNOD or Specialist Requester) and region (A or B). Following the principles of Framework analysis (Ritchie, et al 1980)), we developed an a priori set of codes

and coded the approach forms. We also determined the consent outcomes for Specialist Requesters and SNODS within region A and B and across regions A and B.

2. NHSBT reports and field notes were reviewed including consent rates and performance indicators by region. Two meetings were convened with NHSBT region A pilot leads, Specialist Requesters, Team Managers and Practice Development Specialists and collation of two NHSBT monitoring reports and their final report. Regions C and D were not involved in this aspect of the research. These data provided contextual information and an anchor point to learn from NHSBT professionals' perspectives as to what they felt was working how and why, their key performance indicators, and how they saw the role of the Specialist Requester in the organisation.

3. DoIT and NPT considerations and insights were used to help interpret the overall implementation and outcomes.

Rigour

We adapt Lincoln and Guba's (Lincoln & Guba, 1985) four dimension criteria to establish rigour:

1. Credibility. The 'approach forms' were designed by NHSBT managers and completed by nurses prior to any independent evaluation as soon as practicable after approaching a family. Free text provided scope to add detail around basic demographic details and nurse processes.
2. Transferability. The context of the new UK Specialist Requester and SNOD role have been unpacked in significant detail and mapped alongside recent research.
3. Dependability. Qualitative data extracted from 996 approach forms were independently coded, analysed and checked by two people. Contact was maintained with NHSBT staff at mutual meetings and events where potentially relevant modifications or changes could be shared.
4. Confirmability. Regular research team meetings with the core team helped interpret data and apply to theoretical frameworks, with input from NHSBT co-authors (who are nurses and very senior NHSBT managers) supporting application to the dataset and wider NHSBT contexts.

FINDINGS

The 996 approach forms represent all potential organ donor cases in 30 months in regions A and B (100% response rate). 604 approach forms from region A and 392 approach forms from region B (Figure 2). Of the 996 cases documented on approach forms; 622 families were approached by a Specialist Requester and 374 families were approached by a SNOD. Looking at the 996 cases as a whole across the two regions the consent rate for Specialist Requesters was 74.4% (463/622) and 77.3% for SNODs (289/374). When looking at all 996 cases, we did not see any observable overall differences in the descriptions of the practice of Specialist Requesters compared with SNODs.

Region B had an almost 50/50 ratio of SNOD to Specialist Requester approaches (200 SNOD / 192 Specialist Requester) whereas Region A achieved a much higher Specialist Requester approach ratio with 174 SNODs to 430 Specialist Requester approaches (Figure 2).

The consent rate for Region A Specialist Requesters was 75.8% (326/430) and 71.8% (125/174) for SNODS. Specialist Requesters had a 4% higher consent rate than SNODs in region A. The consent rate for Specialist Requesters in Region B was 71.4% (137/192) and 82% (164/200) for SNODs (Figure 2). SNODs had a 10.6% higher consent rate than Specialist Requesters in region B (Figure 2).

When the cases were stratified, there were 159/996 (16%) cases which documented a change in the family members initial feelings about organ donation (Table 3). Of the 159 there were 98 cases where the SNOD or Specialist Requester was able to influence the family to positively support organ donation. 73/98 (74.5%) were undertaken by a Specialist Requester and 25/98 by a SNOD (25.6%). Of the 73 Specialist Requester approaches, 53 (73%) were undertaken by a Specialist Requester in region A and 20 (27.4%) by region B. Specialist Requesters therefore achieved higher consent rates when supporting family members to change their views from an uncertain or negative to a positive position (Table 3). However, the ability of Specialist Requesters to change the position of family members from negative and uncertain to positive differed by region, with Specialist Requesters in region A being more able to support families to move from a negative or uncertain position to a positive consent outcome (Table 3).

Of the 51 cases in region A where Specialist Requesters were able to change the family members views from an uncertain or a negative, Specialist Requester 1 (SR1) undertook 17/51 of these cases 33.3% whereas SR8 undertook only 1/51 of these cases (2%) (Figure 3). Region B had similar variation over four Specialist Requesters: SR1 in region B approached 8/19 (42.1%) cases and SR4 in region B approached 1/19 (5.3%) case where the family members views were changed to a positive (Figure 3). Specialist Requesters and in particular 2 Specialist Requesters in Region A had a higher consent rate than SNODS, which was not replicated in Region B.

Of interest, 61 cases across region A and B were recorded as moving from uncertain or positive to negative about organ donation. For the majority of these cases SNODs and Specialist Requesters documented a 'pre-approach' (an approach about organ donation made by a person other than a SNOD/Specialist Requester) and therefore were unable to determine the family members initial feelings about organ donation. The cases which turned from positive to negative were mostly DCD cases with time taken to organ donation perceived as too long and other well-known barriers to organ donation documented as the reasons for the change of mind (such as; health systems issues, family do not want surgery to the body, perception that relative had suffering enough, family believe that if their relative wanted to donate they would have told them and disagreements within the family). Specialist Requesters were also not routinely sent to cases where families had already expressed a very positive view of organ donation at the time of referral. This potentially meant that Specialist Requesters were approaching the most complex of cases and SNODs were approaching few or no families who felt negative about organ donation or with other potential barriers such as violent deaths, late referrals or disagreements within the family.

DISCUSSION

Over the 30 month period, Specialist Requesters in the originator NHSBT region A had higher consent rates (4%) than SNODs. The magnitude of positive difference in favour of Specialist Requesters in region A reduced from 19.5% to 4% with a larger sample over 30 months. Similar positive effects of the Specialist Requester were not seen in region B, where SNODs had higher consent rates than Specialist Requesters. This aligns with the initial analysis undertaken by NHSBT - that regions with well-established Specialist Requester roles and were involved in the initial implementation had higher consent rates than SNODs (Madden S et al., 2019). Findings from our longer analysis of processes and outcomes show that region A Specialist Requesters (and in particular two Specialist Requesters) were better than region B Specialist Requesters at getting family members to move from a negative or uncertain position to positively support the organ donation. Thus two Specialist Requesters in particular disproportionately contributed to the difference in consent outcomes. It is not however clear from the data what it is about these specific highly effective Specialist Requesters that made them so effective. The perceptions, experiences and actions that they described on their approach forms were no different to any other approach form, so the ability to support family members to change their position to a positive consent outcome is likely to be related to their personal characteristics and communication skills with family members which cannot be documented on a form. This explanation accords with evidence from the US where despite the absence of evidence concerning their overall effectiveness, Designated Requesters were thought to have better communication skills with family members. Likewise continuous audits in the US still indicate inconsistent and varying consent rates of Designated Requesters despite a specialist role in seeking consent for organ donation in operation since 1999 (Goldberg et al., 2013). Ongoing audits, performance reviews and academic studies in the US continually identify new elements that appear to be associated with higher consent rates. Evidence indicates that it is not just about isolating a specific role to focus on consent but the high-level communication skills, experience, and up to date training of the person making the request (Siminoff et al., 2015).

Neither region A or region B were able to achieve universal Specialist Requester coverage and this impacted the environmental conditions of the intervention as listed in DoIT as an active mechanism for change, and was a (very) necessary and ongoing reconfiguration process as listed in NPT throughout the implementation (table 4).

Region A was also the region that championed Specialist Requesters and originally adapted and implemented the role in the UK. The individuals in region A were selected to be the first Specialist Requesters because they were good at gaining consent from family members. DoIT provides a framework outlining the known characteristics necessary for successful interventions in health systems, including; **Innovation features, target adopters, environmental conditions, Innovation champions and scale up and spread strategies** (Mittman et al., 2014). In a recent realist synthesis review of scaling up complex interventions Willis et al. added that **awareness, confidence, commitment and trust** are additional key mechanisms in successfully scaling up complex interventions in public health. (Willis et al., 2016). Table 4 maps the above characteristics alongside the core actions of Normalisation

Process Theory (NPT) to help explain what was happening in region A as the originator of the intervention and in particular what appeared to be working and why.

It is not however clear if the potential mechanisms that may have influenced the successes seen in Region A were or were not present in region B. The region B manager(s) were committed to implementation, championed the role and worked closely with region A. But fidelity was more affected in region B and adoption was slower. Fewer SNODs were appointed as Specialist Requesters. High staff turnover and sickness, and ongoing reconfigurations with rota coverage meant that fewer SNODs could be trained up. Feedback from stakeholders also suggests that the original intention of recruiting SNODs with high performing consent rates has been difficult to sustain and that anybody who had an interest in the role could become a Specialist Requester when rolled out beyond region A. Of note, the consent rates of Specialist Requesters compared with SNODs in region B, deteriorated over the longer period of time of our analysis. In the initial evaluation consent rates were equal, whereas over a longer period of time SNODs achieved 10.6% higher consent rates than Specialist Requesters in region B, which may reflect the shorter time period for Specialist Requesters to adjust to their role or that other organisational factors described above and in Table 4 were more influential.

The introduction of the Specialist Requester role can also be conceived as a 'disruptive intervention' that did not consistently work as intended in an area of nursing practice associated with complex processes and a complex system (Barros et al., 2015). The Specialist Requester can be considered a 'disruptive intervention' as it created new networks and new organisational cultures involving new roles that had the potential to improve health outcomes and increase the value of health care. The system is considered complex because organisational practices and processes differed within NHSBT regions, individual characteristics of the Specialist Nurses were variable, organ donation is a highly sensitive topic, family member views on organ donation vary widely, family dynamics are unique to each case and vary widely, and the circumstances in which organ donation occurs are associated with acute bereavement and often violent and traumatic circumstances leading to death such as accident or suicide. In theory, the introduction of Specialist Requesters was supposed to displace older systems and ways of doing things, but in the implementation sites there were still too few Specialist Requesters to meet demand and thus the old system had to simultaneously operate alongside the new system.

The Specialist Requester intervention focussed largely on the benefits for; family members (a better experience), transplant patients (increase in consent rates), and providers (SNOD work patterns and rota coverage) rather than implementation issues. It is therefore difficult to unpack if there was an intervention failure or implementation failure or a combination of both.

Irrespective of the fact that there was not much empirical evidence pointing to the success of Designated Requesters in the US, the disappointment and difficulties in scaling up seemingly promising interventions are well known. A 2017 systematic review of scaling up evidence-based practice in primary care concluded that it was unclear if any strategies had been effective as most studies focussed on the patient/provider outcomes and not on scaling-up processes and outcomes (Charif et al., 2017). Mangham et al. suggest that many

interventions fail at the ‘scale up and spread’ stage simply because the resources available during the initial implementation are not available in other contexts (Mangham et al., 2010). Mittman et al. suggest that this failing is due to an overall lack of recognition of heterogeneity and addressing this across settings with regard to needs, circumstances, capabilities, and other factors (Mittman, 2014). Contextual factors surrounding the implementation of complex interventions in practice are known to weigh heavily on their effectiveness. For example, LaRocca et al., in 2012 examined the effectiveness of knowledge translation strategies used in public health and found that no single knowledge translation strategy was effective in all contexts (LaRocca et al., 2012). In fact, they suggested that drawing conclusions about the success rate of any intervention cannot be taken ‘without considering the characteristics of the knowledge that was being transferred, the providers, participants and organizations.’ Greenhalgh et al also acknowledge the challenges of scale up but argue it is, ‘potentially achievable through a combination of different logic models: mechanistic, ecological and social’ (Greenhalgh & Papoutsis, 2019).

Box 2. Greenhalgh’s case examples of mechanistic, ecological and social models.

Reproduced from, ‘Spreading and scaling up innovation and improvement’, *BMJ* 2019;365:l2068

Mechanistic = Implementation science takes a structured and phased approach to developing, replicating, and evaluating an intervention in multiple sites.

Ecological = Complexity science encourages a flexible and adaptive approach to change in a dynamic, self-organising system.

Social = Social science approaches consider why people act in the way they do, especially the organisational and wider social forces that shape and constrain people’s actions.

Region A were leaders and champions of the innovation. Their processes worked from the ‘bottom-up’ and their active mechanisms align with a combination of Greenhalgh’s summary of “*complexity science: spread and scale up as adaptive change* and *Social science: spread and scale-up as social action*” rather than, “*Implementation science: spread and scale-up as structured improvement*” although there were elements of the later evident in the intervention (Greenhalgh & Papoutsis, 2019, pg.1).

While the intervention worked in one setting (region A), we can see indicators of some of the barriers that influence the implementation and scale up of complex interventions e.g. the “implementation fallacy,” which is the assumption that good ideas will be adopted spontaneously (Mittman Brian, 2014). In addition, the mechanisms which made the intervention work in region A (such as the abilities and individual characteristics of specific Specialist Requesters) are not necessarily (easily) transferrable. Rolling out Specialist Requesters without better understandings of what worked and why in region A could for example have the reverse affect: changing perception to a ‘top-down’ intervention driven by policy and targets. Recent studies have shown that this perception in addition to contextual factors can hugely hinder the spread of promising large-scale health interventions (Hoffmann et al., 2014).

Limitations

The paper provides the first comprehensive and largescale process evaluation of implementation of the Specialist requester role in the UK (996 potential organ donor cases over 30 months). However the data collection tools were not prepared by the academic partners and we had no input into the data collection. Due to the short timeframe interviews or focus groups with a wider group SNODs or Specialist Requesters was not possible.

CONCLUSION

Our process evaluation helped identify the potential mechanisms that enabled Specialist Requesters in region A to be more effective than those in region B. In both regions there was insufficient Specialist Requesters to cover the rota as intended but Specialist Requesters in region A were still more effective than those in region B (where SNODs achieved higher consent rates than Specialist Requesters).

Following initial championing, adoption and implementation of the Specialist Requester role and reorganisation of the SNOD workforce in region A, similar benefits were not realised when the intervention was scaled up and implemented in 3 other regions. The complexities of scaling up large scale, disruptive, complex and sensitive interventions such as a specialist role focussed on consent for deceased organ donation needs to consider the ways SNODs turned Specialist Requesters interpret and understand their role in relation to the wider NHSBT workforce and the ways they communicate this within NHSBT. Ongoing consideration needs to be given to the type of person, their skills and training programme as Specialist Requesters. Differing processes and practices within regional teams need to be considered such as availability of resources, the capacity for the intervention to adapt and be flexible in different contexts.

Word count. 4998

Glossary

SNOD – Specialist Nurse in Organ Donation, UK

OPO – Organ Procurement Organisation, USA

Collaborative cases – SNOD and Specialist Requester approaches the family together.

NHSBT – National Health Service Blood and Transplant

NPT – Normalisation Process Theory

DoIT – Diffusion of Innovation Theory

MDT – Multi-Disciplinary Team

DCD – Donation by Circulatory Death

DBD – Donation by Brain Stem Death

WHO – World Health Organisation

TIDieR - Better reporting of interventions: template for intervention description and replication

RINTAG – Research Innovation Technology Advisory Group NHSBT

BBN – Breaking Bad News

WLST – Withdraw Life Sustaining Treatment

BSDT – Brain Stem Death Testing
ED – Emergency Department
ICU – Intensive Care Unit

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Tweetable abstract: Why did Specialist Requesters achieve higher consent rates in one UK region but not elsewhere? Read about their initial implementation in NHS Blood and Transplant in the UK.

Tables and figures

Table 1. Comparisons of Specialist Nurses in Organ Donation and Specialist Requesters background, roles and responsibilities in the UK with Designated Requesters in the US.

Table 2. The TIDieR check list describing the initial implementation and evaluation of Specialist Requesters in the UK. (Hoffmann et al, 2014).

Table 3. Breakdown of cases: regional teams A & B; Specialist Requester/ Specialist Nurse in Organ DONation; Donation by Brain Stem Death/Donation by Circulatory Death pathways; and cases that documented a change in family members initial feelings about their deceased relative becoming an organ donor.

Table 4. Mapping the characteristics of Diffusion of Innovation Theory to unpack mechanisms and applying Normalisation Process Theory to help contextualise what Region A was doing during the intervention

Figure 1. Anonymised graph of NHS Blood and Transplant statistics and analysis comparing Specialist Nurses in Organ Donation and Specialist Requester consent rates in 4 UK regions from October 2016 – September 2017

Figure 2. Total number of potential donor cases, Region A & B Specialist Requester and Specialist Nurse in Organ Donation approaches and consent rates split by region.

Figure 3. Performance chart of 8 individual Specialist Requesters from region A and 4 individual requesters from region B who were able to influence the family to support organ donation when the family member(s) initial views were documented as negative or uncertain.

Supplemental file 1. United States context for organ donation: the introduction of the Designated Requester; Requester training.

Supplemental file 2. United Kingdom contexts for organ donation: Overview of the NHS Blood and Transplant service; Overview of Implementing specialist requesters in the United Kingdom

Appendix 1. The Approach Form